Roll No. | | | | | | | | | | | | **Total No. of Pages : 01**

Total No. of Questions : 06

M.Pharmacy (Pharmacology) (Sem.–2)

CLINICAL RESEARCH & PHARMACOVIGILANCE

Subject Code : MPL-204T

M.Code : 74946

Date of Examination : 04-01-23

Time : 3 Hrs. **Max. Marks: 75**

INSTRUCTIONS TO CANDIDATES :

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carries FIFTEEN marks.**

1. Discuss about origin of International Conference on Harmonization. Discuss about Good Clinical Practice guidelines and their principles.

2. Describe the structure and content of an informed consent process. Discuss about Ethical principles governing informed consent process.

3. Enlist various types and design of clinical studies. Discuss about Cohort, Case control and Cross sectional studies.

4. Describe the objective, contents of an investigator brochure and case report form in a clinical trial.

5. Define Adverse Drug reactions. Classify various types of ADR's. Describe about their detection and reporting methods and severity assessment.

6. Discuss about evaluation of medication safety and establishment of Pharmacovigilance centers in hospitals.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.